Jonathan W. Emord (Pro Hac)
Andrea G. Ferrenz (Pro Hac)
Emord & Associates, P.C.
1800 Alexander Bell Drive, Suite 200
Reston, VA 20191
Phone: (202) 466-6937
Fax: (202) 466-6938

Peggy A. Tomsic (3879)
Tomsic & Peck LLC
136 East South Temple
Suite 800
Salt Lake City, UT 84111
Phone: (801) 532-1995
Fax: (801) 532-4202

Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

NUTRACEUTICAL CORPORATION, et al.,	)	
Plaintiffs,	)	
v.	)	Case No. 2:04CV00409 PGC
ANDREW VON ESCHENBACH, M.D., Commissioner of the U.S. Food and Drug Administration, et al.,	)	
Defendants.	)	

PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT AND PLAINTIFFS' OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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Plaintiffs Nutraceutical Corporation and Solaray, Inc. (collectively "Nutraceutical") submit in a single consolidated pleading this Reply in Support of Plaintiffs' Motion for Summary Judgment and this Opposition to Defendants' Cross-Motion for Summary Judgment. Plaintiffs here refer to Defendants' opposition and cross-motion collectively as "Defendants' Opposition" (abbreviated as "Opp.").[1]

INTRODUCTION

Defendants' statement of purportedly undisputed material facts includes demonstrably false representations. Defendants' argument that the first-ever adulteration "standard" for all dietary supplements (". . . we are articulating a standard for unreasonable risk under 402(f)(1)(A) of the act for the first time . . .," 69 FR 6788, 6794 (Feb. 11, 2004)) was neither a legislative rule nor subject to the Administrative Procedure Act's (APA's) notice-and-comment requirement fails against the weight of apposite precedent and logic. Likewise, Defendants' argument that FDA is free to ban outright a dietary ingredient (ephedrine alkaloids) down to a molecule when in one kind of food, a dietary supplement, but not when in foods in general or in traditional Asian medicines (TAMs) constitutes the quintessence of irrational, arbitrary, and capricious agency action condemnable under the APA. As explained in detail below, on the facts and law, summary judgment should be granted in Plaintiffs' favor.

SUMMARY OF DISPUTED FACTS

Defendants' recitation of the facts contains false representations, some material, some not; Defendants' objections to Plaintiffs' Exhibits A, E, F, and G are unfounded.

[1] Text in bold-faced type contained within any quote herein is Plaintiffs' emphasis added.

The nonmaterial facts. Defendants have alleged as "material fact" representations of harm that, even if true, would not be material to the remanded issues. Those issues concern whether FDA violated the APA (1) by not publishing in the Federal Register notice of its first-ever "unreasonable risk" standard for all dietary supplements and (2) by exempting ephedrine alkaloid containing foods and TAMs from the 2004 Final Rule. Even if Defendants' statements were germane to the remanded issues, they are false (contradicted by the record). The record does not contain any causative proof of harm or corroborated adverse event at 10 mg or less ephedrine alkaloids ("EDS") daily dose amounts. [See Plaintiffs' Motion for Summary Judgment (hereinafter "Motion") at Exh. F (scientific report of former AMA Senior Scientist Dr. Michael John Glade). See Opp. at iv, para. 1; iv-v, para 2 ("After evaluating data, FDA concluded that *all* EDS, regardless of dose, pose a risk of serious adverse events" and stating that *all* increased blood pressure, stroke, heart attack, heart failure, abnormal heart rhythms and death when no record proof exists of harm involving EDS in 10 mg or less daily dose amounts); at vi, para. 10; viii, para. 18; ix, para. 23; x-xi, paras. 27, 28, 29, 31 (none of the harms recited involve EDS at 10 mg or less daily dose amounts)].

As Defendants admitted at trial in 2005, Transcript (hereinafter "Tr.") at 20-21, and as is reflected in the 2004 Final Rule, 69 FR at 6805, Defendants possessed no affirmative evidence of harm at 10 mg or less daily dose amounts and based their conclusion banning low dose levels not on proof of harm but, in an unprecedented fashion, *on the absence of proof of safety*. See Refs. 84, 85, 86 to the 2004 Final Rule; 69 FR at 6805. The 2004 Final Rule unequivocally states FDA banned low doses based *on the absence of proof of safety*, not on proof of harm: ". . . we commissioned a scientific review that was placed in the 2000 docket [Refs. 84 and 85] [i.e.,

unpeer-reviewed letters of opinion by Dr. Mario Inchiosa[2]]. This review concluded that a 'safe dose' of ephedrine alkaloids cannot be identified . . . . We also note that in the 1996 [Food Advisory Committee] meeting, several committee members stated that, based on the available data, no safe level of ephedrine alkaloids could be identified for use in dietary supplements. [Ref. 86]." 69 FR at 6805. The presence of proof that ephedrine alkaloids in daily doses of 10 mg or less harm people is decidedly not the same as the absence of proof of safety at those dose levels. The former is proof of risk of illness or injury; the latter is not.

The material facts. Defendants assert two purported facts that are false and are material to the issues on remand. First, Defendants falsely assert that the ephedra genus of plants has not been used as a food for thousands of years. [Opp. at xiii, para. 1.] Uncontroverted facts in the agency record contradict this extra-record assertion. [See, e.g., Exhibit N attached hereto.[3]]

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[2] In the record below, Defendants depended on three letters of opinion from a Dr. Mario Inchiosa (Refs. 83, 84, and 85) in which Dr. Inchiosa created his own unique unpeer-reviewed and untested hypothetical extrapolation wherein he presumed ephedrine alkaloids would affect the body in a manner indistinguishable from the chemically different and more potent drugs ephedrine and epinephrine. He extrapolated from the studies involving intravenous injection of those drugs, even though the dietary ingredient is orally ingested. He assumed comparable effects, despite the fact that the drugs are very potent inducers of rapid heart contractions and elevated blood pressure and directly affect parts of the body that the dietary ingredient does not. He employed a mathematical model never before used in pharmacology or toxicology to compare the drugs with the dietary ingredient. Based on those unconventional and unprecedented techniques, he concluded that continuous ingestion of 1.5 mg of ephedrine alkaloids every four hours would present a risk of injury comparable to the drugs. Neither Dr. Inchiosa nor anyone else at FDA ever discussed, let alone evaluated clinically, ingestion of 5 mg or less of ephedrine alkaloids consumed twice daily at meal times, the actual dosing conditions of use for the Plaintiffs' product. Dr. Inchiosa's letters were not peer-reviewed. His hypothesis was never tested. His conclusions of toxicity were not based on any clinical testing of the actual dietary ingredient at any dose level, let alone 10 or fewer mg. The drug-dietary ingredient comparison model he invented was not adopted through scientific consensus and is not a standard method for pharmacological or toxicological evaluation.

[3] The Ad Hoc Committee on the Safety of Ma Huang's comments (attached as Exhibit N hereto) include, *inter alia*, the following record submissions on point:

> --"Ephedra, also known as Herba Ephedrae and Ma huang, has been known to mankind for at least 20,000 years, and it has at various times been used as food, in beverages and for healing purposes."
>
> --"The Indo-Aryans knew Ephedra as an edible plant that gave strength and happiness, and combated exhaustion (Hahdihassan, 1981). Though Indo-Aryans traditional[ly] believed that substances conferring longevity were mainly inorganic, Ephedra was considered as a food with similar beneficial properties (Mahdihassan, 1984), and there is strong evidence that the Rigveda [circa 1500 B.C.] references to *soma*

There is no finding in the 2004 Final Rule refuting this record evidence (to be sure, by FDA's action in the 2004 Final Rule exempting from the ban all ephedra "foods," the contrary is plainly indicated), nor did FDA argue that ephedra tea was not a food of long historic use in the original trial or before the 10th Circuit even though those facts were presented by Plaintiffs every step of the way. Defendants' false representation is significant because the arbitrariness and capriciousness of the Final Rule's exclusion of foods is revealed by the fact that the dietary

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actually describe Ephedra juice (Mahdihassan and Mehdi, 1989)."

"Soma, according to the Rigveda, was the drink of longevity which was even given to newborn infants; this Aryan custom was later to be followed by the Romans, and is still practiced among the Parsee of Bombay and in parts of Iran. Lewis and Elvin-Lewis (1977) also report a long history of use of the dried stems of Ephedra gerardiana in Northern India and Pakistan."

"[I]n North America, historical Amerindian use of Ephedra species is well-documented (Moerman, 1986), and includes use of the roots to make bread (Rose, 1972) as well as the stems to make tea (Tyler, 1982). The early settlers may have adopted the latter custom from observation of the Indians, or may have learnt the virtues of such teas from early Chinese immigrants, since during the last 150 years, various Ephedra species have enjoyed use in North America as herbal teas, under names as varied as Mormon Tea, Teamster's Tea, Settler Tea, Squaw Tea, Cowboy Tea, Canutillo, Popotillo, Desert Herb and Ma Huang (Saunders, 1920; Kowalchik and Hylton, 1987)."

"Though Ephedra was also used conventionally as a herb or dietary supplement, or even as food, the pleasant, piney tea, frequently prepared from Ephedra trifurca (Lewis and Elvin-Lewis, 1977) was widely used by Mexicans, Indians and settlers alike, even to the extent of regularly being served in brothels . . ."

"In conclusion, therefore, one may safely say that the Ephedra herb has a long and well documented history of use, both in food applications and for its healing properties."

See also Exh. N at 8 (on the continued use of ephedra in modern times as a food by the Indo-Aryans and the Himalayans).

"Several members of the Ephedraceae are found in North America, where they have traditionally been used to make refreshing vitalizing teas (Saunders, 1920). The Chinese species, E. sinica, was introduced into the Dakotas in the 1930s (Christensen and Hinde, 1936), and may have both spread and hybridized. According to the USDA (1937), Ephedra is an excellent forage crop, and other agricultural studies have shown that Ephedra feeding improves lean to fat ratio in livestock and milk production in milk animals (Kovacevic et al., 1974)."

ingredient in the not-banned food (tea), raw crushed *ephedra sinca*, is precisely the same dietary ingredient in the banned Nutraceutical dietary supplement.

Second, Defendants assert that the 1997 Proposed Rule relied on 21 U.S.C. § 342(f)(1)(A) "as FDA's authority for regulating EDS." [Opp. At vii, para. 12.] Not true. The 1997 Proposed Rule relied on **both** Sections 342(a)(1) of the Act (the "injurious to health" basis) **and** 342(f)(1)(A) (the "significant" and the "unreasonable" risk bases). 62 FR at 30693 (June 4, 1997).[4] The language of the 1997 Proposed Rule unmistakably reveals Defendants' representations are false: Ephedrine alkaloids "shall be deemed adulterated under section **402(a)(1) and (f)(1)(A)** of the act [i.e., 21 U.S.C. § 342(a)(1) and (f)(1)(A)]. FDA is proposing to adopt this provision under sections **402(a)(1), (f)(1)(A),** and 701(a) . . . of the act." 62 FR at 30693. This point is significant. It demonstrates that the "unreasonable risk" "standard" articulated "for the first time" in the 2004 Final Rule (these are FDA's words from the 2004 Final Rule, 69 FR 6788, 6794 (Feb. 11, 2004)[5]) for all dietary supplements, not just ephedrine alkaloids, is a substantive new rule that had not been the subject of prior publication in the Federal Register.

Exhibits A, E, F, and G. Defendants argue that Plaintiffs' Exhibits A, E, F, and G are

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[4] In their Motion, Plaintiffs referred to FDA's reliance on all of these statutory sections in the 1997 Proposed Rule as a "consolidated standard." In response, Defendants misleadingly suggest to the Court that Plaintiffs are contending that the words "consolidated standard" are actually contained in the 1997 Proposed Rule itself. [Opp. at 10.] That is not fair play. In Plaintiffs' Motion, Plaintiffs explain that the term "consolidated standard" is their shorthand reference for the remarkable fact that FDA did indeed propose enforcement against ephedrine alkaloids not based on 21 U.S.C. § 342(f)(1)(A) alone (as Defendants falsely state, Opp. at vii; 11-12) but based on 21 U.S.C. § 342(a)(1) **and** Section 342(f)(1)(A) (including on "significant" risk as well as "unreasonable" risk). Defendants arguments to the contrary are disingenuous, rewriting the actual text in the 1997 Proposed Rule.

[5] These words belie the *post hoc* rationalization FDA now offers the Court. If FDA was not promulgating a substantive standard for the first time, but was simply implementing a rule foreshadowed by the 1997 Proposed Rule, clearly it would not have stated, "we are articulating a standard for unreasonable risk under 402(f)(1)(A) of the act for the first time . . ." 69 FR at 6794. FDA's *post hoc* rationalization is forbidden, see Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 419 (1971). Moreover, accepting that rationalization requires the Court to pretend that FDA did not write the words quoted here from FDA's 2004 Final Rule.

extra-record and may not be considered by this Court. Defendants are patently wrong. Exhibit A is the Solaray Ephedra label in use during the pendency of the rulemaking below. It is of record, having been filed as an attachment to Plaintiffs' April 7, 2003 Comments to the agency (those comments, including the very same Solaray Ephedra label, are appended to Plaintiffs' original Motion as Exhibit D).[6]

Exhibit E is the Affidavit of Nutraceutical Corporation Vice President and Chief Operating Officer Jeffrey A. Hinrichs confirming the contemporaneous perception of Nutraceutical Corporation of the 1997 Proposed Rule at the time Nutraceutical submitted its comments in that rulemaking. Defendants have waived any right to object to the affidavit because they have argued their perception of commenters' statements on this very point. [Opp. at 6, 6n.8, 14n.16.] FDA, moreover, has misconstrued the materiality of the comments (the issue is not whether some commenters perceived a role for assessment of ephedrine alkaloid benefits in reaching an ephedrine adulteration decision but whether FDA gave any notice of its intent to promulgate a new "unreasonable risk" adulteration standard for all dietary supplements, and it did not).[7]

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[6] Defendants' false representation concerning the Solaray label is not an isolated incident. In the May 8, 2006 oral argument before the Tenth Circuit, the Defendants falsely represented that the dosing germane to the case was not 5 mg or less EDS per pill taken no more than twice daily with meals (the actual dosing, see Plaintiffs' Exhibit A) but was a different, higher daily dose, one said to be in the directions for use on "the Solaray label." Defendants misled the Court by relying on an out-dated Solaray label (bearing an FDA date sticker of July 30, 1997, fully six years and seven months before the Feb. 11, 2004 Final Rule) not in use by Plaintiffs during the pendency of the rulemaking, not the dosing that was the subject of Plaintiffs' comments and appeal. See Nutraceutical Corp. v. Crawford, 364 F.Supp.2d 1310, 1315 (D. Utah 2005); Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033, 1035 (10th Cir. 2006). Shortly after the oral argument, Plaintiffs filed a "Motion to Correct Oral Argument Record," revealing the Defendants' false representation and asking the Court to exclude that representation from the record and to include in its stead the actual dosing (which is 5 mg or less EDS per pill taken no more than twice daily with meals). The Tenth Circuit granted that motion in its decision. See 459 F.3d at 1044.

[7] None of the comments cited by Defendants in their Opposition demonstrates an expectation by the commenters that FDA would act outside the scope of an ephedrine alkaloid enforcement action. None reveal an expectation that FDA would incorporate "benefit" within a new adulteration standard for all dietary supplements, one based exclusively on "unreasonable risk" rather than on "significant risk" or "significant" and "unreasonable risk." To the contrary, the comments cited recommend that FDA take into account evidence of benefit as part of the proposed enforcement

Exhibit F contains Nutraceutical Corporation's supplemental comments and scientific report by Michael J. Glade, Ph.D., FACN, CNS, LDN. That exhibit should be part of the record because Plaintiffs could not have anticipated that Defendants would eliminate causation in the Final Rule (contrary to the 1997 Proposed Rule that depended on proof of causation to find adulteration). 62 FR at 30683; 30690; 30693. During the rulemaking, Nutraceutical Corporation filed comments asking FDA to exempt from its adulteration finding ephedrine alkaloids in quantitative amounts of 10 mg or less per daily dose based on a complete absence of affirmative scientific proof showing that those low dose levels caused harm. [Plaintiffs' Motion at Exhs C; D.] FDA never responded to that precise argument in its 2004 Final Rule. FDA never determined, based on scientific evidence, whether ephedrine alkaloids in quantities of 10 mg or less *caused* any adverse physiological effects. Instead, FDA stated in the 2004 Final Rule that "a 'safe dose' of ephedrine alkaloids cannot be identified," banning ephedrine alkaloids completely, down to a molecule, without any proof of causation at low dose levels. 69 FR at 6805. The 2004 Final Rule announced expressly that the "unreasonable risk" "standard" it adopted there for the "first time" could deem risk of illness or injury present without proof of causation. 69 FR at 6798 ("The government's burden of proof for 'unreasonable risk' can be met with any science-based evidence of risk and does not require a showing that the substance has actually caused harm in particular cases"). The 2004 Final Rule materially deviated from the 1997 Proposed Rule. The 1997 proposal was consistent with then existing adulteration precedent; it based adulteration on a determination of the quantitative amount of ephedrine alkaloids that *caused* harm, 62 FR at 30683, 30690 (focusing on evidence of "causality"), 30693. Consequently, after

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action against ephedrine alkaloids, not as part of (the then undisclosed) new standard that would define adulteration for all dietary supplements.

the issuance of the Final Rule and before the institution of suit, Nutraceutical Corporation asked Defendants to address the absence of affirmative proof issue directly (as FDA had not in the rulemaking) and to rule 10 mg or less of EDS per daily dose exempt from its ban based on the absence of any affirmative scientific evidence in the record of illness or injury resulting from ingestion of ephedrine alkaloids in those dose amounts (that conclusion reached by former AMA Senior Scientist Dr. Michael John Glade upon a review of all scientific evidence of record, see Plaintiffs' Motion at Exh. F). Defendants entered that comment into the docket but never responded to it. In the 10th Circuit decision, the Court rejected precisely the same kind of argument for exclusion of evidence that Defendants now raise, based on the fact that Plaintiffs cannot equitably be required to comment during rulemaking on a matter first announced in the Final Rule. See 459 F.3d at 1041 at n.9. That precedent applies here to defeat the Defendants' argument for exclusion.[8]

Exhibit G is the content of an April 19, 2004 speech given shortly after adoption and implementation of the 2004 Final Rule by then Acting FDA Commissioner Lester M. Crawford wherein he explained FDA's intent to use the same standard for banning EDS to evaluate whether comparable action should be taken against the dietary ingredients bitter orange, usnic acid, pyrrolizidine alkaloids, and kava. The exhibit is material because it reveals that FDA had a

[8] In addition, FDA has a habit of altering or amending agency determinations based on scientific information submitted after a decision is published. E.g., "Antiperspirant Drug Products for Over-the-Counter Human Use; Final Monograph; Partial Stay; Reopening of the Administrative Record," 69 FR 61148 (Oct. 15, 2004) (After final monograph was published, two new comments were submitted with new data; FDA stayed parts of the final monograph in response); "Laxative Drug Products for Over-theCounter Human Use; Reopening of the Administrative Record," 68 FR 60302 (Oct. 22, 2003) (FDA received many comments with new data after the administrative record closed; FDA reopened the record to allow for additional new comment and data); "Beverages, Bottled Water; Consumer Surveys; Availability; Reopening of Comment Period," 58 FR 34010 (June 23, 1993) (Manufacturer submitted suvey after close of comment period; FDA reopens comment period for comments on it); "Special Dietary Foods Label Statements; Misleading Statements; Reduced Calorie Labeling for Bread; Revocations of Withdrawal of Proposed Rule," 46 FR 33053 (June 26, 1981) (An industry member filed an objection and request for a hearing after a final rule; FDA reopened the comment period).

present intention to apply the standard for dietary supplement adulteration promulgated in the 2004 Final Rule against other dietary supplements. It is well-established that administrative agencies may not object to evidence of the agency's own pronouncements concerning a rule when those agency documents are "directly related to the decisions made and adverse to the agency's position." Public Citizen v. Heckler, 653 F.Supp. 1229, 1237 (D.D.C. 1986) (Court rejects FDA's attempt to quash evidence that is "indicative of the lack of rationality" of the agency when it says that all raw milk is a known public health risk then refuses to ban all types of raw milk; the court holds this inequitable treatment "the essence of arbitrary action" under the APA).

RESPONSE TO DEFENDANTS' STATEMENT OF UNCONTESTED MATERIAL FACTS

Plaintiffs have no objection to the statement of facts contained in the Defendants' Opp. at paragraphs 3, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, 20, 21, and 32. Plaintiffs object to and deny the purportedly undisputed facts in the following paragraphs.

1. The allegations in paragraph 1 are immaterial and false for the reasons stated in the Summary of Disputed Facts above. They are denied to the extent that they presume, contrary to the findings in the Final Rule, 69 FR at 6805, and without causal proof, that EDS in 10mg or less daily dose amounts are unsafe or present an unreasonable risk of illness or injury. [See also Motion Exh. F (scientific report of Dr. Michael John Glade).]

2. The allegations in paragraph 2 are immaterial for the reasons stated in the Summary of Disputed Facts above. They are denied to the extent that they presume, contrary to the findings in the Final Rule, 69 FR at 6805, and without causal proof, that EDS in 10 mg or less daily dose

amounts are unsafe or present an unreasonable risk of illness or injury. [See Motion Exh. F (scientific report of Dr. Michael John Glade) to the contrary.]

12. The allegations in paragraph 12 are denied as false. The 1997 Proposed Rule did not rely "on 21 U.S.C. § 342(f)(1)(A) as FDA's authority for regulating EDS;" FDA stated in that proposed rule that it was relying on sections 342(a)(1) ("injurious to health"); 342(f)(1)(A) ("significant or unreasonable risk"); and 701(a) (enforcement provision). [See also Summary of Disputed Facts (above) and 4-8 infra.]

18. The allegations in paragraph 18 are immaterial and false for the reasons stated in the Summary of Disputed Facts above. The allegations in paragraph 18 are denied to the extent that they presume, contrary to the findings in the Final Rule, 69 FR at 6805, and without causal proof, that EDS in 10 mg or less daily dose amounts are unsafe or present an unreasonable risk of illness or injury. [See also Motion Exh. F (scientific report of Dr. Michael John Glade).]

19, 22-34.The allegations in paragraphs 19 and 22-34 are immaterial and false for the reasons stated in the Summary of Disputed Facts above. Those allegations are denied to the extent that they presume, contrary to the findings in the Final Rule, 69 FR at 6805, and without causal proof, that EDS in 10 mg or less daily dose amounts are unsafe or present an unreasonable risk of illness or injury. [See also Motion Exh. F (scientific report of Dr. Michael John Glade).]

35. The allegations in paragraph 35 are denied to the extent that Defendants describe ephedra herb tea as a "food additive;" that legal conclusion is barred by apposite precedent. [See 13 infra.] The allegations are also denied to the extent that Defendants imply that TAM is an over-the-counter drug when in the 2004 Final Rule, 69 FR at 6813-6814, the whole herb and

whole herb extract substances described as TAM are not ingredients authorized by FDA for sale as over-the-counter drugs. See 21 C.F.R. § 341.16 et seq.

ARGUMENT

I. DEFENDANTS VIOLATED THE APA NOTICE AND COMMENT REQUIREMENT

A. The "Unreasonable Risk Standard" FDA Adopted in Its 2004 Final Rule Is a Legislative/Substantive Rule by Operation of Law

There is no recorded instance of a federal court permitting an exception to the APA requirement of Federal Register notice for promulgation of a first-ever "standard" (". . . we are articulating a *standard* for unreasonable risk under 402(f)(1)(A) of the act for the first time . . ., 69 FR at 6794"). If the Court were to permit FDA to escape its obligation here, the decision would be unprecedented, and it would cause a designedly "rare" exception to swallow the rule. See Alcaraz v. Block, 746 F.2d 593, 612 (D.C. Cir. 1984) (federal courts "rarely" allow exception to the APA requirement of Federal Register notice with opportunity for comment before promulgation of a new rule).[9]

Section 342(f)(1)(A) of the Act is not self-executing (". . . presents a significant or unreasonable risk of illness or injury"). That language alone does not define an enforceable rule of general applicability. Rather, as FDA implicitly and explicitly recognized when it promulgated its "first-ever" standard in the 2004 Final Rule, the agency was developing new law; it was acting in a quintessentially legislative manner. In 1997, FDA proposed to take

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[9] "[L]egislative functions of administrative agencies shall so far as possible be exercised only upon public participation on notice." Morton v. Ruiz, 415 U.S. 199, 232 (1974) citing generally H.R. Rep. No. 1980, 79th Cong., 2d Sess., 21-23 (1946). In Morton, the Supreme Court explained that agencies must follow the APA notice-and-comment requirement to be well informed and to incorporate public opinion into their rulemaking. Through that APA requirement, Congress intended to prevent agencies from acting arbitrarily or unfairly in the passage of APA legislation. Id. Courts have cautioned that the interpretive rule exception is to be construed *narrowly*. See Alcaraz v. Block, 746 F.2d 593, 612 (D.C. Cir. 1984); National Ass'n of Home Health Agencies v. Schweiker, 690 F.2d 932, 949 (D.C. Cir. 1982). A legislative rule establishes legal requirements, grants rights, imposes obligations, or produces other significant effects on private interest, or it substantially curtails agency discretion in decisions and has present binding effect. Spirit of the Sage Council v. Gale Norton, 294 F.Supp.2d 67 (D.D.C. 2003) citing National Family Planning and Reproductive Health Ass'n Inc. v. Sullivan, 979 F.2d 227 (D.C. Cir. 1992).

enforcement action against ephedrine alkaloids based on a consolidated standard (combining the "injurious to health" provisions of Section 342(a)(1) with the "significant risk" provisions of 342(f)(1)(A) along with the "unreasonable risk" provisions of 342(f)(1)(A), 62 FR at 30693). FDA thus exercised its discretion, at that time, to define an approach entirely different from the standard adopted in the 2004 Final Rule. In 2004, FDA eschewed "injurious to health," eschewed "significant risk," and defined its standard solely in reliance on "unreasonable risk." In 2004, FDA further defined "unreasonable risk" to mean a comparison of risks with benefits. That, the Tenth Circuit has instructed, is the meaning of "unreasonable risk." 459 F.3d at 1038. But that meaning is, itself, not self-executing. Each term, "risk," "benefit," and "comparison" has to be filled with meaning and assigned weights before a "test" using those terms can be applied (and therein lies law-making, the creation of a "standard"). The standard adopted in 2004 was unlike others foreshadowed by the 1997 Proposed Rule that FDA could have adopted. FDA could have defined, as it proposed in 1997, risk to exist at dose and serving levels where harm could be proven causally. 62 FR at 30683; 30690. Instead, in the 2004 Final Rule FDA defined a standard that did not require proof of causation. 69 FR at 6798. Moreover, in the 2004 Final Rule, FDA accepted "any science-based evidence of risk," 69 FR at 6798, but only considered "benefit" if it was one of "health" and was corroborated by "a meaningful totality of the evidence." Id. Perhaps most significantly, FDA could have limited its standard to apply solely against ephedrine alkaloids (FDA's proposal in 1997 was an enforcement action against ephedrine alkaloids, not a proposal to create a new adulteration standard for all dietary supplements). Instead, in 2004, FDA chose to define an adulteration standard for all dietary supplements. Collectively those events reveal the standard that FDA admits was first

promulgated in the Final Rule is a substantive one that imposes new obligations on the regulated class from which extraordinary consequences follow (the destruction of the entire ephedra supplement industry). There can be no doubt that the "standard" promulgated in the 2004 Final Rule is a legislative rule. [10]

Defendants' argument that the rule is not legislative and substantive is legally barred on three grounds. It is barred by the precedent on which they have consistently relied, Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 843-844 (1984); by the Final Rule's statement to the contrary; and by the purpose and effect of the new standard (which imposes new obligations on regulatees). Defendants' attack on the precedent upon which they have consistently relied, Opp. at 15, n.17, is legally untenable. It is black letter law, absent statutory exemptions, that legislative/substantive rules are ordinarily controlled by Chevron. Non-legislative/non-substantive rules are, by contrast, ordinarily controlled by the less deferential standard in Skidmore v. Swift, 323 U.S. 134, 139-140 (1944). See United States v. Mead Corp., 533 U.S. 218, 234-235 (2001). In the 2004 Final Rule and every judicial proceeding concerning it (including the original trial and the Tenth Circuit appeal), even in the Defendants' own Opposition to which we now reply, Opp. at 6, Defendants have argued that the standard promulgated in the 2004 Final Rule is governed by Chevron. Implicit in Defendants' reliance on Chevron is the admission that the rule in question is a legislative/substantive one for

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[10] Defendants' argument that the rule is interpretive rather than substantive rings hollow due to the fact that the rule creates new "obligations" for regulatees and "'legal consequences . . . flow'" from it. See Ctr. for Auto Safety and Public Citizen, Inc. v. NHTSA, 452 F.3d 798, 806 (D.C. Cir. 2006) (citing Bennett v. Spear, 520 U.S. 154, 177-78 (1997); see also Ballesteros v. Ashcroft, 452 F.3d 1153, 1158 (10th Cir. 1981), citing Morton v. Ruiz, 415 U.S. 199, 232 (1974) (legislative rules "affect[] individual rights and obligations"). Before the Final Rule, those who sold supplements could expect to market the products without fear of an adulteration finding *unless the products were shown causally to produce harm at the dose sold*. After the Final Rule, that assurance was eliminated; under the new adulteration "standard" for all dietary supplements, if a dietary supplement is shown to pose a risk at some dose level (a ubiquitous circumstance), FDA may ban it at all dose levels without the government having to prove causation. That change in the law is not merely interpretive, it is substantive.

which Federal Register publication and opportunity for comment is required. As explained in detail below, Defendants by their own admission "articulate[ed] a standard for unreasonable risk under 402(f)(1)(A) of the Act for the first time" in the Final Rule. 69 FR at 6794. If Defendants' argument were accepted, that acceptance would support a reopening of the Tenth Circuit decision (which was based on Chevron, not on Skidmore) to reconsider it under Skidmore.

B. The Legislative/Substantive Rule in the 2004 Final Rule Is Not a "Logical Outgrowth" of the 1997 Proposed Rule and Imposed New Obligations on Regulatees

Defendants' argument that the new adulteration "standard" first articulated in the 2004 Final Rule for all dietary supplements is but a "logical outgrowth" of the 1997 Proposed Rule (making prior notice and publication unnecessary) is equally untenable. In its 1997 Proposed Rule, FDA did not offer the public a proposed **new standard defining adulteration for all dietary supplements** (the very thing it adopted in the 2004 Final Rule). Its proposal recommended, more modestly, an enforcement action exclusively against ephedrine alkaloids shown to cause harm at specific daily serving levels. 62 FR at 30693. FDA sought to enforce 21 U.S.C. § 342(a)(1) ("injurious to health" basis) and 21 U.S.C. § 342(f)(1)(A) ("significant" and "unreasonable" risk of illness or injury) but did not propose creation of a new "unreasonable risk" adulteration "standard" applicable to all dietary supplements. FDA thus substantially exceeded the widest breadth of the 1997 Proposed Rule, when it declared in the 2004 Final Rule a new standard for adulteration for all dietary supplements. That striking move came unheralded by the 1997 Proposed Rule and took the regulated class completely by surprise.

In its Opposition, Defendants misrepresent the content of the 1997 Proposed Rule. Just compare FDA's description of the 1997 Proposed Rule with the actual text of the proposal:

(1) FDA Description: "Nutraceutical is simply incorrect in asserting that FDA established an 'interpretive consolidation' of 21 U.S.C. §§ 342(a)(1) and (f)(1)(A) [in the 1997 Proposed Rule]." [Opp. at 10-11.]

1997 Proposed Rule:

> To reflect this tentative conclusion, FDA is proposing to adopt [new regulatory section] 111.100(a)(1) . . . . under section **402(a)(1) and (f)(1)(A)** of the act. FDA is proposing to adopt this provision under sections 402(a)(1) [21 U.S.C. § **342(a)(1)**], **(f)(1)(A)** [21 U.S.C. § 342(f)(1)(A)], and 701(a) [21 U.S.C. § 371(a)] of the Act."

62 FR at 30693.

(2) FDA Description: "Nutraceutical's view that FDA 'focused on identifying those dose levels that were both injurious to health and that presented a significant and unreasonable risk of illness or injury' in the 1997 Proposed Rule . . . is incorrect." [Opp. at 11.]

1997 Proposed Rule:

> Based on the available evidence . . . the agency tentatively concludes that the use of dietary supplements containing 8 mg or more ephedrine alkaloids per serving may render the dietary supplement ***injurious to health***. The agency **also** tentatively concludes that consumption of supplements that contain this level or more of ephedrine alkaloids presents a ***significant and unreasonable*** risk of illness or injury . . ., ***and that, therefore***, products that contain this or higher levels of ***ephedrine alkaloids are adulterated***.

62 FR at 30693.

> Under section 402(a)(1) of the act, a food, ***including a dietary supplement***, is adulterated if it bears or contains any added or poisonous or deleterious substance that may render it ***injurious to health***. Section 402(f)(1)(A) of the act provides that a dietary supplement is adulterated if it, or one of its ingredients, poses a ***significant or unreasonable risk of injury or illness*** when used as directed . . . Under section 701(a) of the act, FDA has authority to issue regulations for the efficient enforcementof the act. **These sections** authorize FDA to issue a regulation that establishes a level of ephedrine alkaloids that, the available evidence makes clear, will render a dietary supplement adulterated as a matter of law.

62 FR at 30693.

(3) FDA Description: "Only by repeatedly disregarding the plain words of the Proposed Rule could one conclude that FDA initiated the rulemaking process with a view toward basing a determination of adulteration for EDS on a consolidation of different statutory adulteration standards." [Opp. at 11.]

1997 Proposed Rule:

> Eight mg per serving and above represent levels at which the presence of ephedrine alkaloids in a dietary supplement may render the product ***injurious to health and presents a significant and unreasonable risk.***

62 FR at 30693.

(4) FDA Description: ". . .[T]he 1997 Proposed Rule's citation of two different provisions of the FDCA as authority for the proposed restrictions on EDS simply reflects the common and prudent practice of citing all applicable grounds for agency action in rulemaking proceedings." [Opp. at 12-13.]

1997 Proposed Rule: The FDA description is an impermissible *post hoc* rationalization; see above each quoted passage from the 1997 Proposed Rule.[11]

Defendants also erroneously presume that, because the Tenth Circuit held "unreasonable risk" unambiguously meant a comparison of risks with benefits, that statutory interpretation decided an issue not before the appellate court: whether FDA met its APA publication obligation. Not so. Starting from the premise that "unreasonable risk" means a risk-benefit comparison does not address the legality of FDA's failure to serve notice of a new standard of adulteration for all dietary supplements. In the 1997 Proposed Rule, FDA recommended an

[11] Federal courts prohibit agencies from replacing the rationale articulated in the agency's decision with one invented anew in argument to a court. See Citizens to Preserve Overton Park, 401 U.S. at 419.

adulteration enforcement action against ephedrine alkaloids and asked parties to identify the dose level at which ephedrine alkaloids *caused* harm, proposing a ban at those dose levels and above. The new adulteration standard in the 2004 Final Rule excludes causation as an element of proof of risk, 69 FR at 6798. FDA could have kept that bedrock principle of adulteration law in place.[12] It did not. FDA could have made the risk-benefit comparison scientifically valid by demanding that the level and degree of science required to show "risk" be the same as that required to show health "benefit." It did not. FDA declared that "any science-based evidence of risk [would suffice to establish adulteration] [without requiring] a showing that the substance has actually caused harm," 69 FR at 6798. By contrast, FDA required that the evidence of "health benefit" only be taken into account if it is "supported by a meaningful totality of the evidence." Id. That lop-sided, non-causal risk-benefit approach permits even an infinitesimal risk to establish adulteration unless counterweighed by a significant health benefit. That test applicable to all dietary supplements is nowhere mentioned in the 1997 Proposed Rule and is not foreshadowed by it.

Defendants engage in yet another sleight of hand by arguing that a few commenters' recommendations that FDA employ an analysis for ephedrine alkaloids involving a balancing of risk with benefit meant that they anticipated FDA would adopt its new adulteration standard for all dietary supplements. Not so. The commenters were responding to the 1997 Proposed Rule

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[12] The dose-response relationship has been a central underpinning of adulteration law and science, the very principle "on which the science of toxicology is based." Dose-Response Relationships in Toxicology, Extension Toxicology Network (1993) (pmep.cee.cornell.edu/profiles/extonet/TIB/dose-response.html); see also United States v. Lexington Mill Co., 232 U.S. 399, 412 (1914). The concept has been the grand and irreducible tenet of toxicology since at least the 16th Century. In the early 1600's, Swiss Physician Philippus Theophrastus Aureolus Bombastus von Hohlenheim Paracelsus (Paracelsus) wrote, "[a]ll things are poison and nothing is without poison. Solely the dose determines that a thing is not a poison." J.L. Goodman, "The Traditional Toxicological Paradigm Is Correct: Dose Influences Mechanism," 106 Environ. Health Perspectives 285, 288 (1988). Until the 2004 Final Rule, the dose-response relationship, the so-called Paracelsian axiom, had been embedded in adulteration law.

which did not propose adoption of a new standard for dietary supplement adulteration, only adulteration enforcement against ephedrine alkaloids predicated on proof of causality between quantity consumed and harms resulting. In Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 549-550 (D.C. Cir. 1983), the court held that an agency "cannot bootstrap notice from a comment" unless the agency at least described with "reasonable specificity" the "range of alternatives being considered."

No hint exists in the 1997 proposal that a new universal dietary supplement adulteration standard was in the offing. FDA never stated an intention to derive a new dietary supplement adulteration standard exclusively from the "unreasonable risk" phraseology in 21 U.S.C. § 342(f)(1)(A) to the exclusion of the "significant risk" language (indeed, in the 1997 Proposed Rule FDA stated that it acted pursuant to the "injurious to health" language in 21 U.S.C. § 342(a)(1) and the "significant" and the "unreasonable" risk language in 21 U.S.C. § 342(f)(1)(A), 62 FR at 30693). FDA never stated an intention to delete from its adulteration assessment proof of causality (indeed, FDA stated that it intended to identify the dose at which illness or injury was *caused* and hold that dose and above adulterated, 62 FR at 30683; 30690; 30693). No commenter could reasonably assume that FDA would leap from an enforcement action against ephedrine alkaloids to the promulgation of a new standard of adulteration for all dietary supplements. Given the content of the 1997 Proposed Rule, the commenters could not have known or reasonably anticipated, at the time of their submittals, that FDA would rely on "benefit" information for use as an input in a test that would accept "any science-based evidence of risk" as proof of adulteration without "requir[ing] a showing that the substance had actually caused harm in particular cases" and would deem that evidence determinative of adulteration absent proof of health benefit by "a meaningful totality of the evidence."

It is also well-established that FDA may not "locate notice [in] comments." Shell Oil Co. v. EPA, 950 F.2d 741, 757 (D.C. Cir. 1991). Only when specific passages in the proposed rule reveal the final rule to be a logical outgrowth do comments suggest adequacy of notice. Id. There is no foundation here for the promulgation of the 2004 Final Rule adulteration standard affecting all dietary supplements in the 1997 Proposed Rule. The new standard is not a logical outgrowth of an ephedrine alkaloid enforcement action; it is an independent legislative rule, a power grab, not foreshadowed by the 1997 Proposed Rule.[13]

The 1997 Proposed Rule and the interim notices of April 13, 200xxx, 65 FR 17474, and March 5, 2003, 68 FR 10417, did not "fairly appraise" the public "of the nature of the rulemaking." United Steelworkers of Am. v. Marshall, 647 F.2d 1189, 1221 (D.C. Cir. 1980). None were on notice that the FDA was going to go beyond an enforcement action against ephedrine alkaloids (under Section 701(a) of the Act) to establish a new adulteration standard for all dietary supplements. The 2004 Final Rule differed in far more than mere "particulars from [the] proposed rule," Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 546-47 (D.C. Cir. 1983). The FDA's unheralded declaration of a new adulteration standard for all dietary supplements constituted, at a minimum, "more surprise than notice," Air Transp. Ass'n of Am. v. FAA, 169 F.3d 1, 7 (D.C. Cir. 1999), particularly because, before the Rule, FDA gave

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[13] Defendants claim that Nutraceutical failed to raise the differences between the 2004 Final Rule and the 1997 Proposed Rule in its trial brief. [Opp. at 13.] The argument is factually and legally incompetent. When Nutraceutical argued that the 2004 Final Rule violated the APA Federal Register notice and comment provisions because it created a new rule not previously the subject of notice and comment, Nutraceutical Complaint at 10-11; original Memo in Support of Motion at 21-22; original Opposition and Reply at 28-34, Nutraceutical raised the very issue here litigated and made the very argument Defendants claim is lacking. Courts do not reject argument when it arises under issues raised in the complaint and in the briefs, even when later articulated at more length or with greater specificity. See Yee v. City of Escondido, 503 U.S. 519, 534 (1992) (once a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they made below) (citations omitted). Indeed, the purpose of the federal rules is the avoidance of prejudice. There is in his Honor's Order on scheduling a full and fair opportunity to address every point raised in argument under this issue.

no clear sign that it would do more than take enforcement action against ephedrine alkaloids.

Fertilizer Inst. v. EPA, 935 F.2d 1303 (D.C. Cir. 1991), a case cited by Defendants, actually supports the proposition that Defendants created a substantive rule. Fertilizer Inst. examined whether a rule creates new duties independent of statutory language (in which case it is legislative, not interpretive). 935 F.2d at 1309. "To determine whether [a rule] is interpretive, the true emphasis must be on the 'legal base upon which the rule rests.'" Id. Here, without question, the rule imposes duties on the regulated class independent of the statutory language. The statutory language does not go so far as to establish a standard for risk, for benefit, or for comparison of the two. It does not determine whether the standard would apply to ephedrine alkaloids or to all dietary supplements. It does not dispense with the need for proof of causality. The promulgation of a standard on all of those points is an APA legislative function; it is a law-making function. In The Rise and Fall of Administrative Law, 72 Chi.-Kent L. Rev. 953, 962 (1997), Judge Richard A. Posner of the Seventh Circuit writes:

> For a rule to be interpretive, it is not enough, I believe that the rule is consistent with the purpose of the statute that it is interpreting; for that is equally true of any valid legislative rule. A valid interpretive rule must be derivable from the statute that it implements by a process fairly to be described as interpretive; that is, there must be a path that runs from the statute to the rule, rather than merely consistency between the statute and the rule.

The "standard" FDA promulgated in the 2004 Final Rule was not policy or process implementing a statutory directive; it was by FDA's own admission in the 2004 Final Rule, the creation of a first-ever standard. The standard is new law; it holds that any science-based evidence of risk establishes "risk" sufficient for a finding of adulteration without need for proof of causation, 69 FR at 6798, and it holds that only "a meaningful totality of the evidence" of health benefit establishes "benefit" worth weighing against risk. Id. It is the "standard," not the

statute, that permits an infinitesimal risk of illness or injury to beget a determination of adulteration absent significant countervailing evidence of health benefit. Before the adoption of the standard, the regulated class should have been afforded the opportunity to comment on it. They were denied that right and, in the denial, FDA violated its APA legal duty.

II. DEFENDANTS VIOLATED THE APA PROHIBITION AGAINST ARBITRARY AND CAPRICIOUS DECISION-MAKING BY EXEMPTING FROM THE 2004 FINAL RULE ALL EPHEDRINE ALKALOID-CONTAINING FOODS AND TAMS

FDA's exemptions of ephedrine alkaloid containing foods and TAMs from the 2004 Final Rule are arbitrary and capricious in violation of the APA. Defendants' arguments that the exemptions do not violate the APA are predicated on a misconstruction of the governing statutory law and cannot be cured by speculation concerning future FDA action against the exempt foods and TAMs. The Final Rule exemptions have created an irrational and incoherent regulatory regime that works against FDA's public health mission. Contrary to Defendants' argument, dietary supplements (including dietary ingredients) are not separate and distinct from foods under the Act. Indeed, both dietary supplements and dietary ingredients are "foods" under the Act. 21 U.S.C. § 321(ff) explicitly states: "a dietary supplement shall be deemed to be a food within the meaning of this Act." Section 321(f) similarly states that a "food" is "an article used for food or drink for man . . ." and includes "articles used for components of any such article," including dietary ingredients. 21 U.S.C. § 321(f). The statutory language of 21 U.S.C. § 350b(a)(1) reveals that "dietary ingredients" are inextricably intertwined with both foods and supplements: "The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered."

Moreover, Defendants are wrong when they argue that 21 U.S.C. § 342(f)(1)(A) only

applies to "dietary supplements." [Opp. at 7.] In fact, Section 342(f)(1)(A) is a subpart of the "Adulterated Food" Section, 21 U.S.C. § 342, which governs foods, dietary supplements, and dietary ingredients. Under the Act, a dietary supplement can consist of one or more "dietary ingredients." 21 U.S.C. § 321(ff)(1). 21 U.S.C. § 342(f)(1)(A) applies to both "dietary supplements" and "dietary ingredients" and defines both as adulterated if they "present[] a significant or unreasonable risk of illness or injury. . ."

Defendants' argument that they did not act in an arbitrary and capricious manner when they adopted the "food exemption" is untenable. Under the 2004 Final Rule, the dietary ingredient ephedrine alkaloids present an unreasonable risk of illness or injury at every dose level, down to a molecule, when in a dietary supplement and are thus adulterated. Under the same Rule, those very same alkaloids are exempt from the Final Rule ban when they are in a traditional food such as ephedra tea. In other words, Nutraceutical's raw crushed *ephedra sinica* herb is banned if placed in a dietary supplement, but if placed in a tea bag, voila, the substance is not banned by the Rule.

Defendants try to blunt the irrationally sharp edge of their distinction by suggesting that FDA could take enforcement action against the food at some later date, perhaps by arguing that the food is an unapproved food additive [Opp. at 8-9.] That argument is irrelevant and incompetent. FDA cannot avoid responsibility for an arbitrary and capricious agency action on the pledge that it might in the future take steps to lessen the impact of the Rule's defects. That is a penultimate *post hoc* rationalization forbidden by the courts. See Citizens to Preserve Overton Park, 401 U.S. at 419. The Court's focus is necessarily on the agency's present action and whether that action is arbitrary and capricious. FDA adopted a categorical exemption from the Rule of all ephedrine alkaloid containing foods, ignoring the fact that the statute makes that move

legally nonsensical (dietary supplements are foods!).

Of course, FDA could have stated that ephedrine alkaloid containing foods, including dietary supplements, were adulterated. For example, the 1997 Proposed Rule concerned and referred to the dietary ingredient, relied on all 21 U.S.C. § 342(a)(1) and (f)(1)(A), and spoke not only of doses (in reference to supplements) but also of servings (in reference to foods). Thus, a complete ban on foods containing ephedrine alkaloids in the Final Rule would have been rational. Instead, FDA adopted an irrational categorical exclusion of foods in the Final Rule, while at the same time banning dietary supplements. That food exclusion is irrational because, if FDA's contention that ephedrine alkaloids present an "unreasonable risk" at every dose level is given credence, how can FDA fulfill its public health mission by exempting those same alkaloids when in foods?

Defendants lamely reargue the twice judicially condemned proposition that ephedra tea is an unapproved "food additive." Opp. at 8-9; see United States v. Two Plastic Drums . . ., 984 F.2d 814, 820 (7th Cir. 1993); United States v. 29 Cartons of an Article of Food . . . Oakmont Inv. Co., 987 F.2d 33, 37 (1st Cir. 1993). Defendants would have the Court believe that the herb, when steeped in water for tea, is not a food but is a "food additive." That argument implies the counterintuitive, that water is the food and the herb is the additive. In two of the most condemnatory decisions against FDA in its history, the First and Seventh Circuits held this argument malapropos and rejected it: "It defies common sense to say a substance can be a 'food additive' when there is no (other) food to which it is added." 29 Cartons, 987 F.2d at 37. As the court derisively and presciently observed (as if anticipating the present case), "it would seem,

even the addition of water to food would make the food [water] a food additive." 984 F.2d at 819.[14]

FDA's exemption of ephedrine alkaloid containing teas and dietary supplements when marketed as TAM also renders the Final Rule arbitrary and capricious. 69 FR at 6814. TAM frequently uses the same raw crushed *ephedra sinica* herb that Nutraceutical placed in its gelatin capsules. The Final Rule thus produces the incongruous and irrational result of banning raw crushed *ephedra sinica* herb from dietary supplements but allowing the very same substance to be exempt from the ban when sold as TAMs.[15]

FDA has adopted a convoluted, irrational, and capricious regulatory scheme, one that is contrary to its public health mission. If FDA is to be believed (that ephedrine alkaloids present an unreasonable risk to public health even down to a molecule), then pursuit of protection for public health under the Act demands consistent treatment of the very substance deemed toxic whether sold as a food, a dietary ingredient in a dietary supplement, or an ingredient in TAM. FDA must be forced to render its new standard for dietary supplement adulteration consistent and in harmony with the entire Act, particularly its provisions on foods and on food substances sold as unregulated medicines in traditional markets.

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[14] Congress in adopting the DSHEA reiterated this condemnation of FDA's misuse of the food adulteration provision. See SEN. REP. NO. 103-410 at 21 (1994).

[15] FDA has not approved whole herbs or whole herb extracts as active ingredients in over-the-counter ephedrine-containing drugs, see 21 C.F.R. 341.16 et seq., thus the exemption is made in contemplation of the fact that these TAMs are outside the OTC regime (belying Defendants' misleading *post hoc* rationalization in the Opp. at xii; 8n.9). Whole herb and whole herb extract ephedra, recognized in the Final Rule as a TAM, 69 FR at 6814, are outside FDA's OTC drug monograph system and, thus, not regulated under it.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Honorable Court deny Defendants' cross-motion for summary judgment and grant Plaintiffs' motion and the relief requested therein.

Dated this 9th day of February, 2007.

Respectfully submitted,

SOLARAY, INC. AND
NUTRACEUTICAL CORPORATION

By: /s/_____

Jonathan W. Emord
Andrea G. Ferrenz
Katie Bond
Robert G. Morley
Emord & Associates, P.C.
1800 Alexander Bell Drive, Suite 200
Reston, VA 20191
Phone: (202) 466-6937
Fax: (202) 466-6938

By: /s/_____

Peggy A. Tomsic
Tomsic & Peck LLC
136 East South Temple
Suite 800
Salt Lake City, UT 84111
Phone: (801) 532-1995
Fax: (801) 532-4202

CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of February, 2007, I electronically filed a true and correct copy of the foregoing PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT AND PLAINTIFFS' OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT with the Clerk of the Court using the CM/ECF system which sent notification of such filing to the following:

John K. Mangum
U.S. Attorneys Office
185 South State Street
Salt Lake City, UT 84111
John.mangum@usdoj.gov

Mark L. Josephs
Trial Attorney
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
Mark.josephs@usdoj.gov

TOMSIC & PECK LLC

/s/ Peggy A. Tomsic
Peggy A. Tomsic
Attorneys for Plaintiffs